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09/997,855	11/29/2001	Jerome Segal	70802.01	6694

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/997,855

Applicant(s)

SEGAL ET AL.

Examiner

Jennifer J Maynard

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 40-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-38 and 45-88 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2 & 3.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

Applicant's preliminary amendment filed 04 October 2002, deleted the brief description corresponding to Figures 2a, 3a, 5a and 6a, however those figure labels still exist in Drawing Sheet No. 1. Appropriate correction is required.

The drawings are objected to because there are two figures labeled "FIG. 8a", it is believed that the figure on Drawing Sheet No. 2 was intended to be labeled Figure 9, because it corresponds to the brief description in Applicant's specification. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to because there are two figures labeled "FIG. 12" on Drawing Sheet No. 4. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The specification is objected to because of the following informalities: Page 14, line 19 refers to Figures 2a, 3a, 5a and 6a, however the brief descriptions to these figures were deleted via Applicant's preliminary amendment filed 04 October 2002. Appropriate correction is required.

### *Claim Objections*

Claim 31 is objected to because of the following informalities: Claim 31, lines 8-9, recite “said cylindrically shaped expansion member *mesh*”, previously in line 7 Applicant claims “a cylindrically shaped expansion member”. The Examiner can not ascertain whether Applicant intended to further limit the structure to a “mesh”, or merely made a mistake in the Amendment submitted on 12 December 2003 by failing to delete “mesh” from the body of the claim. Appropriate correction is required.

Claim 32 is objected to because of the following informalities: Claim 32, line 4, recites “a predetermined side”. The Examiner believes it was Applicant’s intent to recite “a predetermined site”. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31, 32, 34, 35, 37, 38, 46, 47, 53, 61, 64-68, 74, 82 and 85-88 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Brown, III et al. (US 6,219,577 B1).

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Brown, III et al. discloses an iontophoresis, electroporation and combination catheter for local drug delivery to arteries and other body tissues, comprising, a catheter (10) having distal end (14), a proximal end (12), and an iontophoretic transport means (24), the catheter having one lumen (see Figure 3) or more lumens (see Figure 4); a cylindrically shaped expansion member (20) coated or impregnated with a drug or other therapeutic agent positioned on the distal end of the catheter, the cylindrically shaped expansion member having a first contracted diameter (see Figure 1) and a second expanded diameter (see Figure 2), the second expanded diameter being larger than the first contracted diameter; see Column 8, lines 13-27, Column 9, lines 1-26; Column 10, lines 13-17 and lines 35-68; Column 11, lines 22-63; Column 14, lines 17-68; and Column 15, lines 1-22 and lines 62-63.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Gencheff et al. (US 5,423,744 A).

Brown, III et al. discloses the invention as claimed with the exception of the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire.

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Gencheff et al. discloses a catheter system for the deployment of biological material , as shown in Figures 7-10, comprising the method step of positioning a guidewire in the body passageway, and wherein the advancing step is accomplished by threading the expansion member over the guidewire, see Column 10, line 60 through Column 11, line 20.

It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s disclosed method of use with the added steps of positioning a guidewire in the body passageway, and threading the expansion member over the guidewire, so as to more effectively control placement of the device at the treatment site.

Claims 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Dubrul et al. (US 6,450,989 A).

Brown, III et al. discloses the invention as claimed with the exception of the cylindrically shaped expansion member comprising a first plurality of flexible elongate elements helically wound in a first direction or rotation and a second plurality of flexible elongate elements helically wound in a second direction of rotation to form a braid.

Dubrul et al. discloses a dilating and support apparatus comprising a dilation mechanism (9), as depicted in Figures 4-A and 4-B, made of an open, mesh metal braid, which allows for perfusion therethrough and is formed by a "Maypole" dance of filament carriers to create a zigzag pattern, wherein one filament moves helically clockwise and the other moves helically counter-clockwise, see Column 13, line 35 through Column 14, line 28; Column 17, lines 30-31; and Column 21, line 4 through Column 22, line 55.

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It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with an open, mesh braid as taught by Dubrul et al. so as to increase the amount of surface area of the device in contact with the vessel wall thereby enabling more controlled and accurate delivery of medicament to affected wall tissue.

Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Segal (US 5,527,282 A).

Brown, III et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like.

Segal discloses a vascular dilatation device for localized delivery of heparin, TPA, hirudin or various anti-thrombin agents, see Column 10, lines 55-61.

It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s catheter for local drug delivery with heparin delivery as taught by Segal, so as to prevent clotting of the blood adjacent the dilation device.

Claims 48, 49, 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Tsugita (US 6,142,987 A).

Brown, III et al. discloses the invention as claimed with the exception an anticoagulant, such as heparin or the like.

Tsugita discloses an endovascular filter device coated with heparin and heparinoids, see Column 5, lines 31-33.

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It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with a heparin/heparinoid coating as taught by Tsugita, so as to reduce thrombi formation of the flexible elongate elements which comprise the expansion member thus ensuring adequate sustained perfusion therethrough.

Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Lennox (US 6,280,411 B1), Palasis et al. (US 6,369,039 B1), or Naimark et al. (US 6,638,246 B1).

Brown, III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 50-52, 54-58, 62, 63, 71-79, 83 and 84.

Lennox (Column 4, line 22 through Column 5, line 35), Palasis et al. (Column 4, line 64 through Column 6, line 22), and Naimark et al. (Column 8, line 50 through Column 10, line 23), all individually, discloses a device for localized delivery of drug agents comprising an expansion member (210, 120, 10/20A/20B/30/40A/40B/50/60/80A/80B, respectively) coated with a medicament comprising a promoter of vascular cell growth, a transcriptional activator, an inhibitor of vascular cell growth, a growth factor receptor antagonist, a cholesterol-lowering agents, a vasodilating agent, an agent that interferes with endogenous vasoactive mechanisms, estrogen, a smooth muscle inhibitor, a compound that inhibits cellular proliferation, and paclitaxel.

It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with a variety of drugs as taught by



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Lennox, Palasis et al. or Naimark et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

Claims 59, 60, 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 6,219,577 B1) in view of Hanson et al. (US 5,985,307A).

Brown, III et al. discloses the invention as claimed with the exception of Applicant's claimed medicament groups as outlined in Applicant's Claims 59, 60, 80 and 81.

Hanson et al. (Column 18, line 50 through Column 19, line 33; and Column 26, line 62 through Column 27, line 3) discloses a device for localized delivery of drug agents comprising an expansion member (50) containing a medicament comprising an agent that modulates intracellular calcium binding proteins, and a receptor blocker for contractile agonists.

It would have been obvious to one having ordinary skill in the art to have modified Brown, III et al.'s cylindrically shaped expansion member with a variety of drugs as taught by Hanson et al., so as to enable treatment of a variety of conditions including localized disease and/or vessel occlusion.

***Allowable Subject Matter***

Claim 39 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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